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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,009	08/06/2002	Carolyn K. Goldman	NIH-05111	5287

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EXAMINER	
JIANG, DONG	

ART UNIT	PAPER NUMBER
1646	

MAIL DATE	DELIVERY MODE
08/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/089,009	GOLDMAN ET AL.	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,5,9,11-15,23 and 26-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,5,9,11-15,23 and 26-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED OFFICE ACTION

The request filed on 15 June 2007 for a Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 10/089,009 is acceptable, and a RCE has been established. An action on the RCE follows.

Applicant's amendment filed on 15 June 2007 is acknowledged and entered. Following the amendment, claims 22, 24 and 25 are canceled, claims 1, 3, 12, 27 and 29 are amended.

Currently, claims 1, 3, 5, 9, 11-15, 23 and 26-29 are pending and under consideration.

Note, the status identifier of claim 9 is "Currently Amended", which does not seem to be correct because there is no amendment indicated for the claim.

Withdrawal of Objections and Rejections:

All objections and rejections of claims 22, 24 and 25 are moot as the applicant has canceled the claims.

Rejections under 35 U.S.C. 112:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, 5, 9, 11-15, 23 and 26-29 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record set forth in the previous Office Actions mailed on 6/16/06 and 11/1/06, and for the reasons below.

There is no argument toward this rejection in the instant response.

Further, *even if* claims 1, 3, 5, 23 and 26-29 were enabled, enablement would not be commensurate in scope with claim 9 and its dependent claims, which are directed to a method for purifying an IL-2R associated polypeptide using an antibody thereto. However, the specification fails to provide or disclose such an antibody. Given the fact that the claim does not specify any particular IL-2R associated polypeptide to be purified, it encompasses any or all polypeptides associated with IL-2R, including those unknown. Thus, although making antibodies to a known specific polypeptide is routine in the art, it is impossible for one skilled in the art to make an antibody to an unknown IL-2R associated polypeptide in order to use the claimed method for the purification of the IL-2R associated polypeptide. The skilled artisan would not know how to make a commensurate number of species, and it would require undue experimentation make encompassed IL-2R associated polypeptides prior to use the claimed invention in its full scope.

Rejections Over Prior Art:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3, 5, 9, 11-15, 23 and 26-29 remain rejected under 35 U.S.C. 102(b) as being anticipated by, or, in the alternative, under 35 U.S.C. 103(a) as obvious over Colamonici et al. (J. Immunol., 1990, 145:155-160), for the reasons of record set forth in the previous Office Action mailed on 6/304, 4/19/05, 10/18/05, 6/16/06 and 11/1/06, and for the reasons below.

Applicants argument filed on 15 June 2007 has been fully considered, but is not deemed persuasive for reasons below.

At page 5-6 of the response, the applicant argues that in view of the claim amendments, the inventive compositions now comprise polypeptides expressed from Kit 225 and YT cells - cell lines not disclosed in the Colamonici reference, that it is improper to compare the polypeptides disclosed in Colamonici with the claimed composition comprising novel IL-2 receptor associated polypeptides as Colamonici relied on a different cell source than either Kit 225 or YT cells. This argument is not persuasive because the specification and the claims indicate that the same two polypeptides exist in HuT102, Kit225, MT1, and YT cells (page 25, lines 8-26, for example). As such, eliminating HuT102 cell in the claims does not change nature of the two polypeptides, and therefore, the claims are still anticipated by or obvious over the cited prior art reference. Note, *if* applicants argue that the two polypeptides in Kit225 and YT cells differ from that in HuT102 cell, then, the specification has not provided any written description for such polypeptides.

Applicants further argue, on page 6 of the response, that Colamonici also does not render the claims obvious as Colamonici does not disclose or suggest an IL-2 receptor associated protein expressed by Kit 225 or YT cells that is capable of forming a complex with the monoclonal antibody produced by the hybridoma PTA-82, and Colamonici does not disclose a polypeptide having a MW of about 32-34 kDa or about 26-28 kDa, and that thus, in view of the deficiencies in Colamonici, one of ordinary skill in the art would not reasonably rely on the teachings or suggestions of Colamonici to arrive at the claimed invention. This argument is not persuasive because Colamonici never tested PTA-82 antibody. As such, the examiner is unable to determine whether the prior art disclosure possesses the unrecited characteristics or property.

With these conditions, where the (product or apparatus or method or product by process) seems to be identical except that the prior art is silent to the characteristic or property claimed, then the burden shifts to applicant to *provide evidence* that the prior art would neither anticipate nor render obvious the claimed invention. Note the case law of *In re Best* 195 USPQ 430, 433 (CCPA 1977). With respect to MW, it is well known that SDS-PAGE is not the most accurate way for determination of MW of a polypeptide, and, as addressed in the previous Office Actions, MW of a polypeptide may vary in SDS-PAGE by from experiment to experiment, depending upon several factors such as different gel concentrations and running time. Therefore, it cannot be used as the sole evidence to distinguish two molecules when their MW is close, which is the case in the instant situation, especially in the presence of the evidence indicating that the claimed molecules are the same as that of the prior art, such as that both are isolated from the same cell, and both are associated with IL-2R.

Conclusion:

No claim is allowed.

Advisory Information:

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Dong Jiang

Dong Jiang, Ph.D
Patent Examiner
AU1646
8/18/07